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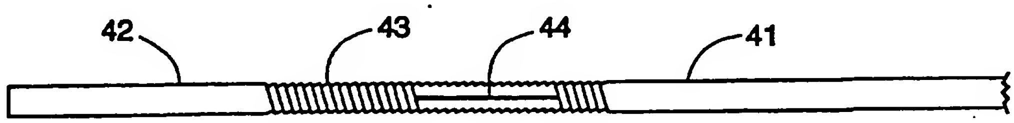

(57) Abstract

A guide catheter is formed from the combination of a tubular member and one or more rods insertable and movable longitudinally within the tubular member. The tubular member has a large central lumen to accommodate working catheters, and a shape memory which forms a curved segment in the tubular member. The rod has one or more substantially straight segments of sufficient stiffness to straighten out portions of the curvature imposed by the shape memory. In certain embodiments of the invention, the rod also contains a more flexible segment which permits part of the curvature of the shape memory to remain. Movement of the rod along the length of the curvature imposed by the shape memory permits the user to adjust the length, shape and location of the curve in the guide catheter, depending on the relative lengths of the segments and the shape of the curvature imposed by the shape memory.

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COMPOSITE GUIDE CATHETER OF ADJUSTABLE SHAPE

BACKGROUND OF THE INVENTION

This invention resides in the technology of guide catheters, which are relatively large lumen catheters for use in cardiology, urology, gastroenterology, and other procedures involving insertion of catheters into bodily passages with curved shapes or branching. Guide catheters are specially shaped to provide a passage to a region of interest inside or at the end of the bodily passage, and their lumens are used to direct functional catheters such as therapeutic, imaging or diagnostic catheters to the region. A guide catheter specially designed for heart surgery, for example, is inserted through the vasculature and into the aorta of a patient and is preshaped in a specific manner to place the distal tip of the catheter inside one of the coronary ostia. With the catheter thus positioned, the large lumen and the pre-imposed shape of the catheter permit it to serve as a guide channel through which smaller catheters which do not have a pre-imposed shape can be advanced to the ostium and beyond to reach locations of interest inside the coronary arterial system.

Guide catheters are available in a wide variety of shapes to follow the contours of the bodily passages for which they are intended. Those of skill in the art recognize these different shapes by names such as Judkins Right, Judkins Left, Amplatz Right, Amplatz Left, Bentson, Shepherd Hook, Cobra, Headhunter, Sidewinder, Newton, Sones and others, each formed into a different shape. In addition, many of these different shapes are manufactured in gradations of size or curvature to accommodate individual patients.

One example of a type of guide catheter which is available in gradations of size, and which serves as an illustration of the needs addressed by the present invention are the catheters known as Judkins Left. The distal end of a Judkins Left catheter is formed into a hook, giving the catheter in its relaxed form a shape resembling the letter "J." Near the tip of the hook is an additional bend. This bend is commonly referred to as the "first curve" or "primary curve" and is located approximately 1 cm or less from the distal tip, while the curve corresponding to the lowest point of the letter "J" is referred to as the "secondary curve". The center of curvature of the secondary curve is generally about 3.5 cm to about 6 cm from the primary curve.

When the catheter is inserted through the aorta, the "J" shape is distorted to follow the aortic arch, but the portion extending from the secondary curve to the distal tip

maintains its curvature. The primary curve places the distal tip of the catheter in the left coronary ostium and a short distance inside the artery, while the secondary curve contacts the wall of the aorta on the side opposite the ostium. The contact continues for a short distance in the proximal direction, and terminates in a "tertiary curve" at the point where the guide catheter separates from the aortic wall. This length of contact between the guide catheter and the aortic wall anchors the Judkins Left catheter in position so that it will serve as a secure guide for the smaller therapeutic or diagnostic catheters to be inserted through it. Other guide catheters, including those for the coronary system as well as those for other bodily regions, have similar distal bends to direct the distal tips into specific branch passages, plus locations along the catheter length where the catheter contacts an internal wall for stabilization.

The dimensions of these bodily passages differ from one patient to the next, and a guide catheter of the appropriate dimensions must be used. In Judkins Left catheters, for example, an important factor in stabilizing the catheter is the angle of the segment between the primary and secondary curves and the axis of the ostium when the guide catheter is in place, the axis of the ostium being generally transverse to the axis of the aorta. This angle is established by the distance between the primary and secondary curves, and for an aortic root of given dimensions, the angle will be greater when this distance is greater. For optimal anchoring stability, this angle is an acute angle of about 10°. Distal tips entering the ostium at greater angles are at serious risk of becoming dislodged when functional catheters are inserted through the guide catheter. The dimensions of the aortic arch and ascending aorta differ from one patient to the next, however, and one must select from among the range of available sizes of Judkins Left guide catheters the one size having the right dimensions for the patient undergoing treatment. In this type of procedures as well as other involving the use of guide catheters, therefore, operating rooms are equipped with a full range of sizes so that quick exchanges can be made as needed.

Since measurements of these bodily passages cannot be taken prior to selecting the appropriate guide catheter, the physician often relies on certain visualization means incorporated in the catheter itself to determine that the catheter is properly positioned. If the catheter cannot be properly positioned, it must be removed and replaced with one of a different size, and this may have to be repeated until an acceptable angle is achieved. This presents disadvantages to the procedure. Cost, for example, is a critical factor in these procedures, and each exchange increases the cost to the patient. In addition, the risk of infection is increased since the major potential sources of infection are skin contaminants and contamination from the operators, both which are introduced at the insertion site. Also, the risk of trauma to the vessels receiving the catheters is increased when multiple insertions are performed.

SUMMARY OF THE INVENTION

The problems noted above as well as other problems associated with guide catheters of the prior art are addressed by the present invention, which resides in a guide catheter with a curvature which is changeable either in location, degree, length, or combinations of these features, and in which the change can be made from the proximal end of the catheter so that adjustments can be made with the catheter already in place inside the bodily vessel.

The catheter of the present invention is one of composite construction, including a tubular member with an extended region of curvature and a straightening rod capable of insertion into the tubular member to straighten out portions of the curvature. The curvature may be any type of non-linear shape, depending on the use or type of catheter, or on the particular known type of guide catheter which the catheter of the present invention is intended as a substitute for. The curvature may thus be a wave-form curvature, a loop, an arc or part of a wave or loop, a loop with multiple turns, or any other kind of curved shape. A curvature in the form of an arc can vary in terms of the radius of curvature, whether the radius is constant or varies along the arc, and the total angular rotation of the arc. A curvature in the form of a loop can vary in terms of the number of turns, the radius of curvature of the loop, whether the radius is constant or varies along the length of the loop, and the location of the loop relative to the length of the tubular member.

For catheters designed to replace Judkins Left catheters, the curvature is a loop which corresponds to the secondary curve in a conventional Judkins Left catheter and the uncurved length exceeds the length of the secondary curve. The straightening rod is segmented, with at least one segment sufficiently stiff to resist bending and at least one relatively flexible segment. The relatively stiff segment or segments are substantially straight and sufficiently rigid to straighten out the tubular member loop along the portions of the curvature which these segments pass through, while the flexible segment is sufficiently flexible to accommodate the curvature. Analogous effects are achieved with other catheters in which the position of the curve varies. Examples are catheters designed to replace Sones and Shepherd Hook catheters.

For catheters designed to replace Judkins Right catheters, the curvature is an arc which conforms in shape to the arc in the largest size Judkins Right catheter. The straightening rod does not contain a flexible segment; instead, it is entirely of a relatively stiff, substantially straight construction. When advanced into the catheter in successive increments, the rod successively shortens the arc from the proximal end of the arc.

Further examples will be readily apparent to those skilled in the art.

The tubular member is an elongate body with a bendable yet resilient construction and a shape memory. When the tubular member is relaxed, its shape memory causes it to

form the curvature referred to above. The tendency to form the curvature is overcome, however, by the straightening rod, or by the stiff segment or segments of the rod. In embodiments in which the rod also contains one or more flexible segments, these segments permit the curvature in the tubular member to remain in the portion of the member where these segments are in contact with the curvature. In the case of a loop, the remaining curvature is thus less than that of the full loop, and the position of the remaining portion of the loop is controlled by the location of the rod relative to the tubular member, *i.e.*, the position of the flexible parts of the rod inside the limits of the portion of the tubular member that would otherwise form the loop. The variability in shape and/or dimensions of the tubular member with the rod inside it will thus depend on how many turns are contained in the relaxed loop, the radius of curvature of the relaxed loop and whether the radius is constant or variable along the length of the loop, whether the loop begins at the distal end of the catheter or is separated from the distal end by a non-looped segment, and how long that segment is, the number and arrangement of flexible and non-flexible segments in the straightening rod, and the lengths of these segments. Similar considerations apply to embodiments in which the curvature is an arc rather than a loop. Thus, by selecting appropriate values and ranges for each of these dimensional variables, the concepts of this invention may be implemented to produce catheters of a wide variety of shapes, for use as adjustable replacements for many of the fixed-shape guide catheters presently in use. This includes catheters with hooks, loops, S-shaped curves, and other shapes.

The straightening rod can be retained by the tubular member in a variety of ways, such as for example by a lumen within the tubular member separate from the larger central lumen which serves as a channel for functional catheters. The rod can then be slid back and forth along the length of the tubular member to move the flexible segment or segments of the rod relative to the loop in the tubular member, and thereby retain the curvature of different portions of the loop. This can be done from the proximal end of the catheter after the catheter has been placed in position with its distal region inside the patient's body.

The less flexible segments of the straightening rod, and particularly the proximal segment, will in general not be completely rigid, but will be flexible only to the extent necessary to permit passage of the tubular member through the bodily passages as needed to reach the site of interest. Curvature can thus be imposed on these sections, and accordingly on the guide catheter as a whole, by the bodily passages themselves, thereby overcoming the stiffness in these sections. The straightening of portions of the looped segment is likewise limited by the shape or curvature of the bodily passage.

These and other features and advantages of the invention are explained in detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts one example of a tubular member representing one component of a composite guide catheter in accordance with the present invention.

FIG. 2 depicts a straightening rod for use with the tubular member of FIG. 1, and thereby forming the second component of a composite guide catheter in accordance with the present invention.

FIG. 3 depicts the two components of FIGS. 1 and 2 combined, with the tubular member in cutaway to render visible the straightening rod inside it.

FIG. 4 depicts the composite guide catheter of FIG. 3 inside an aorta, showing the catheter in several configurations differing by the degree of insertion of the straightening member.

FIG. 5 depicts one example of the construction of the straightening rod of FIG. 2 in partial cross section.

FIG. 6 depicts a second example of the construction of the straightening rod of FIG. 2.

FIG. 7 depicts a third example of the construction of the straightening rod of FIG. 2.

FIG. 8 depicts a second example of a tubular member for use as part of a composite guide catheter in accordance with the present invention.

FIG. 9 depicts a straightening rod for use with the tubular member of FIG. 8.

FIG. 10 depicts the tubular member of FIG. 8 and the straightening rod of FIG. 9 combined.

FIG. 11 is a second view of the tubular member of FIG. 8 and the straightening rod of FIG. 9 combined, with the straightening rod further advanced inside the tubular member.

FIG. 12 depicts a third example of a tubular member for use as part of a composite guide catheter in accordance with the present invention.

FIG. 13 depicts a straightening rod for use with the tubular member of FIG. 12.

FIG. 14 depicts the tubular member of FIG. 12 and the straightening rod of FIG. 13 combined.

FIG. 15 is a second view of the tubular member of FIG. 12 and the straightening rod of FIG. 13 combined, with the straightening rod further advanced inside the tubular member.

FIG, 16 depicts a composite guide catheter of the present invention in transverse cross section.

DETAILED DESCRIPTION OF THE INVENTION AND PREFERRED EMBODIMENTS

As indicated above, the concepts of the invention can be embodied in catheter constructions ranging widely in shape, size and configuration, for different bodily passages and clinical procedures. To promote a better understanding of the invention, however, the following discussion will primarily address three types of catheters -- Judkins Left, Judkins Right and Shepherd Hook. It will be apparent to those of skill in the art, however, that the principles discussed in relation to this class will be applicable to other classes as well. The constructions shown in FIGS. **1** through **7** represent specific examples of how the invention can be applied to achieve the Judkins Left shape; FIGS. **8** through **11** show an example designed to achieve the Shepherd Hook shape; and FIGS. **12** through **15** show an example designed to achieve the Judkins Right shape.

To achieve a composite catheter of the invention corresponding to any of these three types of guide catheter (as well as any others), the elongate tubular member referred to above will be one with external dimensions similar to, and most often the same as, the corresponding guide catheters of the prior art, except for the curvature in the region where the curvature is varied by the position of the straightening rod. This difference is eliminated upon the insertion of the straightening rod, whereupon the tubular member is forced into a shape closely approximating that of the conventional prior art catheter.

The extended length of the tubular member will generally range from about 50 cm to about 150 cm, preferably from about 90 cm to about 110 cm. The diameter of the member will most often be in the range of about 4 French (F, where 1F = 0.33 mm) to about 12F, and preferably from about 6F to about 11F. The central lumen of the tubular member will most often have a diameter of from about 3F to about 11F, preferably from about 5F to about 10F. The lumen will be large enough to accommodate and permit the insertion and withdrawal of working catheters such as angioplasty catheters, atherectomy catheters, laser ablation catheters, imaging catheters, and other types of interventional and diagnostic catheters.

FIG. **1** illustrates a tubular member **11** in accordance with the invention, without a straightening rod, and therefore in a relaxed condition. As shown, the tubular member includes a distal tip **12** with a slight bend, a looped segment **13**, and a relatively straight segment **14** between the distal end and the looped segment. The bent distal tip **12**, which is the primary curve of the tubular member, is generally about 5 mm to about 10 mm in length, forming an angle of from about 120° to about 150° with the straight portion of the catheter which is immediately adjacent to it. The distance of the straight segment **14** extending from the primary curve **12** to the beginning of the looped segment **13** is generally from about 1 cm to about 10 cm, and preferably from about 2 cm to about 7 cm.

The looped segment 13 when in the relaxed condition as shown in FIG. 1 forms a loop with a total angular rotation of at least about 1.25π radians. In preferred embodiments of the invention, the total angular rotation of this loop is at least about 1.5π radians. In a presently preferred embodiment, the total angular rotation of the loop is about 1.83π radians (330°). The extended length of the looped segment will generally range from about 15 mm to about 100 mm, and preferably from about 25 mm to about 75 mm. In a presently preferred embodiment, this extended length is about 55 mm. The radius of curvature in the looped segment when relaxed will be from about 5 mm to about 20 mm, and preferably about 10 mm.

FIG. 2 illustrates a straightening rod 21 which contains two straightening segments -- a distal segment 22 and a proximal segment 23 -- and one flexible segment 24 between the two straightening segments. Straightening rods for other catheter shapes may have one straightening and two flexible segments, only one segment of each, two or more segments of each, or other arrangements or combinations depending on the tubular member and its ultimate shape. In all such arrangements, an interface between adjacent flexible and straightening segments will reside within the confines of the tubular member loop when the parts are assembled, and the adjustment is achieved by moving the location of the interface. In the embodiment shown in FIG. 2, there are two interfaces 25, 26, and at least one remains within the confines of the loop.

FIG. 3 illustrates the assembled guide catheter, with the straightening rod inserted in the tubular member. The angular rotation of the loop is reduced to a 180° (π radians) turn by the distal 22 and proximal 23 segments of the straightening rod, while the flexible segment 24 permits the curvature to remain over a shortened length although one which is sufficient to achieve the 180° turn.

The amount of curvature which remains in the loop of the tubular member when the straightening rod is inserted, and the distance between the remaining loop curvature and the distal tip of the tubular member, are determined by the length of the flexible intermediate segment 24 of the straightening rod, and the position of this segment relative to the loop 13 (FIG. 1). The flexible segment 24 of the rod is shorter than the extended length of the loop, and the shorter the flexible segment is, the lesser the degree and length of curvature at the secondary curve of the assembled guide catheter. In preferred embodiments of this invention, the flexible segment 24 of the straightening rod will have a length ranging from about 0.1 to about 0.8 times the extended length of the looped segment of the tubular member. With a tubular member having a loop of the dimensions given above, a preferred straightening rod will be one with the flexible segment 24 having an uncurved length of from about 5 mm to about 50 mm, and preferably about 15 mm to about 40 mm, but at least about 5 mm shorter, and preferably at least about 15 mm shorter, than the extended length of the looped segment. In a presently preferred

embodiment, the flexible segment 24 is about 0.5 times the extended length of the looped segment of the tubular member, and is about 25 mm in length.

The further the flexible segment is inserted distally along the length of the loop, the smaller the distance between the secondary curve and the distal end of the tubular member, and consequently the smaller the approach angle that this portion of the guide catheter will assume inside the aortic root relative to the axis of the ostium in which the primary curve at the distal tip is inserted. FIG. 4 shows the assembled guide catheter in position with its distal region in the aorta, close to the aortic root 31, with the distal tip 32 inside the ostium 33 of the right coronary artery. The catheter is shown in various gradations of shape 34, 35, 36, 37, with corresponding gradations in the location of the secondary curve 38 along the aortic wall, and in the approach angle α of the catheter toward the ostium 33. These gradations are the result of different lengths for the distance between the secondary curve 38 and the catheter's distal tip 32, and are achieved by moving the straightening rod relative to the tubular member.

Examples of configurations and constructions for the straightening rod are shown in FIGS. 5, 6 and 7. In the example of FIG. 5, the relatively stiff proximal 41 and distal 42 segments of the rod are separated by an intermediate flexible segment 43 which consists of a coil spring coiled around a central wire 44 (the view is shown in partial cross section to expose the wire). The coil spring 43 has no stiffness in any direction perpendicular to the length of the rod and will bend or curve in any transverse direction. When placed inside a lumen of similar diameter, however, the coil spring 43 together with the central wire 44 can push or pull the distal segment 42. The proximal and distal segments as well as the spring and wire may be made from a solid metallic material, such as stainless steel or aluminum, appropriately tempered, or nonmetallic materials. The outer diameter of the coil spring is approximately equal to the outer diameters of the stiffer proximal and distal segments of the rod, to minimize any discontinuities and thereby facilitate the longitudinal sliding of the rod inside the tubular member.

In the rod construction shown in FIG. 6, the relatively stiff proximal 45 and distal 46 segments are separated by an intermediate segment 47 which is more flexible by virtue of a smaller diameter. All segments may be of solid metallic composition, with the same metal or alloy being used for each. Alternatively, the rod may be formed of a polymeric material which can be softened by heat and drawn to a small diameter.

In the rod construction shown in FIG. 7, the intermediate segment 48 is formed from a different material of construction than the proximal 49 and distal 50 segments, the material of the intermediate segment being one which is inherently more flexible than that used for the proximal and distal segments. The difference in flexibility may be achieved by using different metal alloys or different polymers, or by using composites of different compositions, or by the same metallic materials or polymers although treated differently to

affect grain size, chain length, or any other parameter which affects flexibility. As in the embodiment of FIG. 5, it is preferred that the three segments have the same outer diameter for ease of movement within the tubular member.

Turning next to FIGS. 8 through 11, a composite catheter in accordance with this invention which is designed to substitute for a prior art Shepherd Hook-type catheter, is shown. The tubular member 51 without the straightening rod is shown in FIG. 8. The tubular member has a curved segment 52 and a hook 53 at the distal end, the curved segment separated from the hook by a short straight length 54. The hook 53 corresponds to the primary curve of the Shepherd Hook catheter, and the curved segment 52 supplies the curvature for the secondary curve. The angular rotation of the curved segment 52 considerably exceeds the angular rotation of the secondary curve of the conventional Shepherd Hook catheter.

FIG. 9 depicts the straightening rod 56. Here, as in the straightening rod in FIG. 2, the rod contains two straightening segments -- one distal 57 and one proximal 58 -- separated by a flexible segment 59. The flexible segment 59 is relatively short compared to the flexible segment 24 of the straightening rod of FIG. 2, and thereby permits less of the curve in the tubular member to remain. This is illustrated in FIGS. 10 and 11, and comparing these Figures to FIG. 3. In FIGS. 10 and 11, the straightening rod 56 is inserted in the tubular member 51 to two different depths. In each case, the only curvature remaining in the tubular member from the curved segment is the small length where the flexible segment 59 of the straightening rod resides, the two straightening segments 57, 58 eliminating the curvature in the portions where they reside.

The composite catheter shown in FIGS. 12 through 15 differs from those of the preceding figures, but is also within the scope of the invention. The tubular member 61, as shown in FIG. 12 without any straightening rod inserted, has the same shape as a large Judkins Right guide catheter, with a bent distal tip 62 and a long arc 63 with a large radius of curvature, close to the distal tip. The angular rotation of the arc is less than 1.0π.

The straightening rod 66, as shown in FIG. 13, does not have both rigid and flexible segments, but is instead uniformly rigid for its entire length. Insertion of the rod into the tubular member achieves the shape modifications shown in FIGS. 14 and 15. By straightening out the proximal end of the arc 63 to varying distances along the arc, the rod shortens the arc to successively shorter lengths 67, 68. The three conditions shown in FIGS. 12, 14 and 15, respectively approximate three gradations in shape of the Judkins Right catheter.

In any of the three examples illustrated above, as well as other shapes and configurations within the scope of this invention, the number of straightening rods used with a single tubular member may vary. The use of two or more straightening rods offers advantages of increased control and less stress on individual straightening rods, with a

lowered risk of breakage. In a presently preferred embodiment, three rods are used in conjunction with a single tubular element.

The shape memory of the tubular member may be inherent in the tubular member itself. Alternatively, the shape memory may be imparted and maintained by one or more rods separate from the straightening rods. These rods, which may be termed "spring rods," may be held stationary, and preferably embedded or otherwise affixed, inside the tubular member so that their position within the tubular member is not variable. The spring rods will have a looped segment corresponding to the looped segment desired in the shape of the tubular member, plus a resiliency which permits their curvature to be overcome by the stiff portions of the straightening rods, and to regain the curvature when the straightening rods are advanced or retracted such that the stiff portions are replaced by the intermediate flexible portion. In a presently preferred embodiment, two such spring rods are incorporated in a single tubular member.

Methods by which a straightening rod is attached to or installed inside the tubular member may vary. This is true of spring rods as well. The central lumen of the tubular member can serve as a conduit for insertion of these rods, while still leaving room for working catheters. This is less preferred, however, than the use of separate lumens.

An example of a tubular member with separate lumens for the working catheters, straightening rods and spring rods is shown in FIG. **16**. The central lumen **71** through which the working catheters pass is approximately circular in cross section, preferably of the dimensions cited above, and is slightly eccentric relative to the tubular member **72** itself. Adjacent to the central lumen are a wide, shallow lumen **73** which accommodates three straightening rods **74**, and two small lumens **75**, **76** of circular cross section, each of which accommodates a spring rod **77**, **78**. The straightening rod lumen **73** provides a relatively loose fit for the straightening rods **74** to permit the straightening rods to be slid readily along the length of the lumen by hand from the proximal end of the catheter. The spring rod lumens **75**, **76** may be of a tighter fit since the spring rods will generally be inserted by the manufacturer and will not be manipulated by the user during the typical medical procedure. The lumens for the straightening and spring rods are preferably positioned on the side of the tubular member facing the loop or the curvature of the secondary curve.

Manipulation of the straightening rod(s) is performed at the proximal end of the tubular member, outside the patient's body. Manipulation is readily performed by hand, with the operator assisted by visualization of the distal tip of the catheter. Visualization may be achieved by conventional means. Fluoroscopy, for example, is one of the most common such means and can be used conveniently in the present invention. Movement and securement of a straightening rod relative to the tubular member can be achieved at the proximal end by simple mechanical means. Examples are a threaded knob, a ratchet-

type mechanism, or various kinds of toothed or locking mechanisms which can be manipulated by hand and would be readily apparent to those skilled in the art. One presently favored structure is a toothed track on a stationary member to which the tubular member is mounted, and a spring-loaded catch on the mobile member to which the straightening rod is mounted, the catch mounted through a pivot to a toothed wheel. When the wheel is pushed by the user's thumb to engage the track, the catch is lifted away from engagement with the track. Turning of the wheel while pressing it against the track by the user's thumb moves the mobile member relative to the stationary member, and release of the wheel causes the catch to engage the track, locking the members relative to each other. Many other mechanisms can be substituted for similar ease of manipulation.

The foregoing is offered primarily for purposes of illustration. It will be readily apparent to those skilled in the art that the number of components, their shapes, materials of construction, methods of use and arrangement in the composite guide catheter described herein may be further modified or substituted in various ways without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A composite guide catheter comprising:

an elongate tubular member having a proximal end and a distal end, said tubular member being resiliently flexible and having a shape memory defining a curved segment separated from said distal end by at most about 10 cm;

a straightening rod capable of being received within said tubular member, said straightening rod comprising a relatively rigid segment occupying at least a portion of its length, said relatively rigid segment being of sufficient rigidity to substantially straighten any curvature imposed by said shape memory on whatever portion of said tubular member said relatively rigid segment is received in; and

receiving means in said tubular member for receiving said straightening rod in a manner permitting longitudinal movement of said said straightening rod within said curved segment, to selectively straighten a portion of said curved segment, the length of said selectively straightened portion varying with the distance by which said straightening rod is inserted into said tubular member.

2. A composite guide catheter in accordance with claim 1 in which said curved segment is an arc having a total angular rotation of less than about 1.0π radians.

3. A composite guide catheter in accordance with claim 1 in which said curved segment is a loop having a total angular rotation of at least about 1.25π radians.

4. A composite guide catheter in accordance with claim 1 in which said curved segment is a loop having a total angular rotation of at least about 1.5π radians.

5. A composite guide catheter in accordance with claim 1 in which said curved segment is separated from said distal end by from about 2 cm to about 7 cm.

6. A composite guide catheter in accordance with claim 1 in which said relatively rigid segment occupies the entire length of said straightening rod.

7. A composite guide catheter in accordance with claim 1 comprising at least two of said straightening rods, and said receiving means are sized to receive all of said straightening rods.

8. A composite guide catheter in accordance with claim **1** in which said tubular member contains a primary lumen to allow passage of a functional catheter, and said receiving means is a secondary lumen in said tubular member.

9. A composite guide catheter in accordance with claim **1** in which said shape memory of said elongate tubular member is imparted thereto by at least one spring rod embedded in said tubular member, said at least one spring rod when relaxed having a looped segment corresponding to the looped segment defined by said shape memory.

10. A composite guide catheter in accordance with claim **9** comprising at least two said spring rods embedded in said tubular member.

11. A composite guide catheter in accordance with claim **1** in which said relatively rigid segment occupies a portion of the length of said straightening rod and is defined as a first rod segment, said straightening rod further comprising a second rod segment of sufficient flexibility to allow whatever portion of said tubular member said second rod segment is received in to conform to said shape memory.

12. A composite guide catheter in accordance with claim **11** in which second rod segment is located distally relative to said first rod segment.

13. A composite guide catheter in accordance with claim **11** in which said second rod segment is of a length ranging from about 0.1 to about 0.8 of the length of said curved segment of said tubular member.

14. A composite guide catheter in accordance with claim **11** in which said straightening rod further comprises a third rod segment of sufficient rigidity to substantially straighten any curvature imposed by said shape memory on whatever portion of said tubular member said third rod segment is received in, said first and third rod segments separated by said second rod segment, and said second rod segment being of substantially shorter length than said curved segment of said tubular member.

15. A composite guide catheter in accordance with claim **14** in which said first and third rod segments are cylinders of continuous solid construction, and said second rod segment is comprised of a coil, said cylinders and said coil all being substantially equal in outer diameter.

16. A composite guide catheter in accordance with claim **14** in which said first, second and third rod segments are cylinders of continuous solid construction, said second rod segment having an outer diameter sufficiently less than the diameters of said proximal and distal segments to provide flexibility to said second rod segment.

17. A composite guide catheter in accordance with claim **14** in which said first, second and third rod segments are cylinders of continuous solid construction with substantially equal diameters, said first and third rod segments being formed of a first material of construction and said second rod segment being formed of a second material of construction of greater flexibility than said first material of construction.

18. A composite guide catheter in accordance with claim **1** in which:

said relatively rigid segment occupies a portion of the length of said straightening rod and is defined as a first rod segment, said straightening rod further comprising a second rod segment of sufficient flexibility to allow whatever portion of said tubular member said second rod segment is received in to conform to said shape memory, and a third rod segment of sufficient rigidity to substantially straighten any curvature imposed by said shape memory on whatever portion of said tubular member said third rod segment is received in, said first and third rod segments separated by said second rod segment, and said second rod segment being of substantially shorter length than said curved segment of said tubular member; and

said curved segment is a loop having a total angular rotation of at least about 1.25π radians and an uncoiled length of from about 15 mm to about 100 mm, said second rod segment being from about 5 mm to about 50 mm in length and at least about 5 mm shorter than said uncoiled length of said loop.

19. A composite guide catheter in accordance with claim **18** in which said loop has an uncoiled length of from about 25 mm to about 75 mm, and said second rod segment has an uncurved length of from about 15 mm to about 40 mm and is at least about 15 mm shorter than said looped segment.

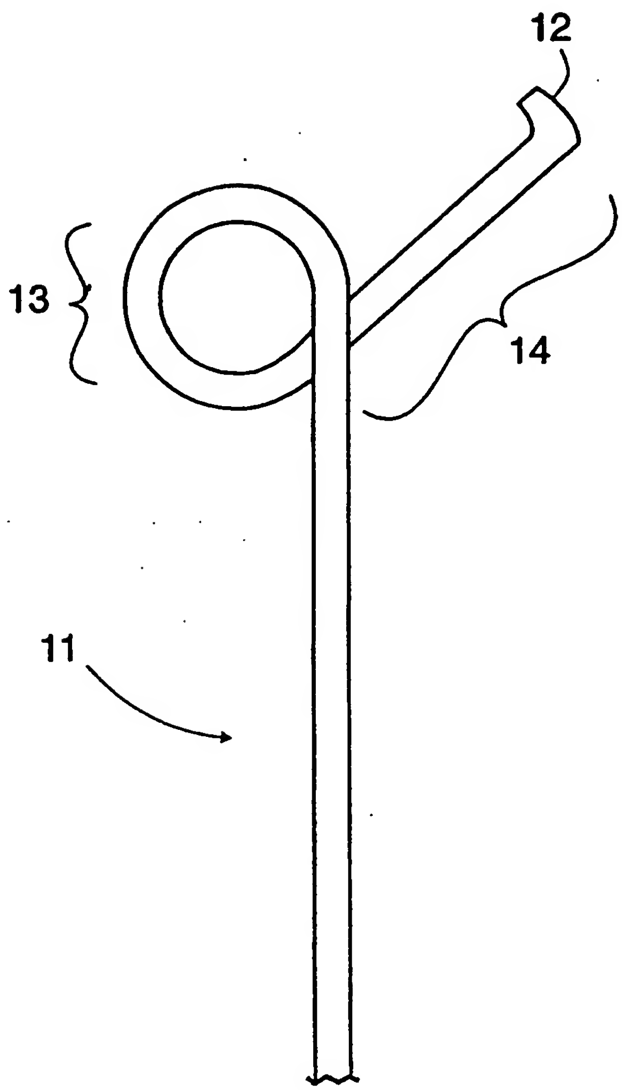

Fig. 1

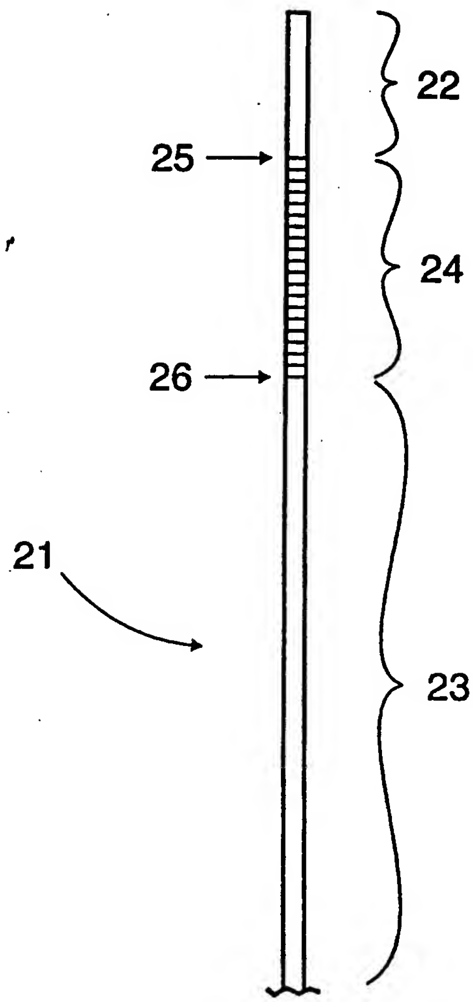

Fig. 2

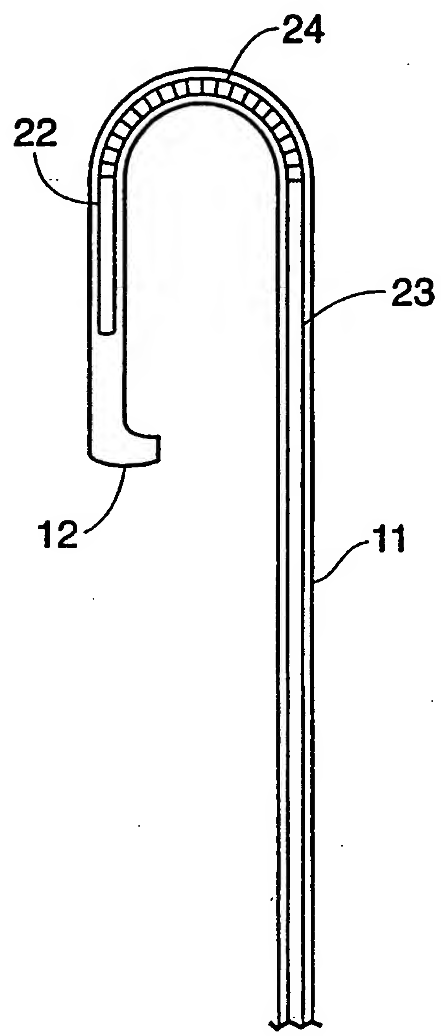

Fig. 3

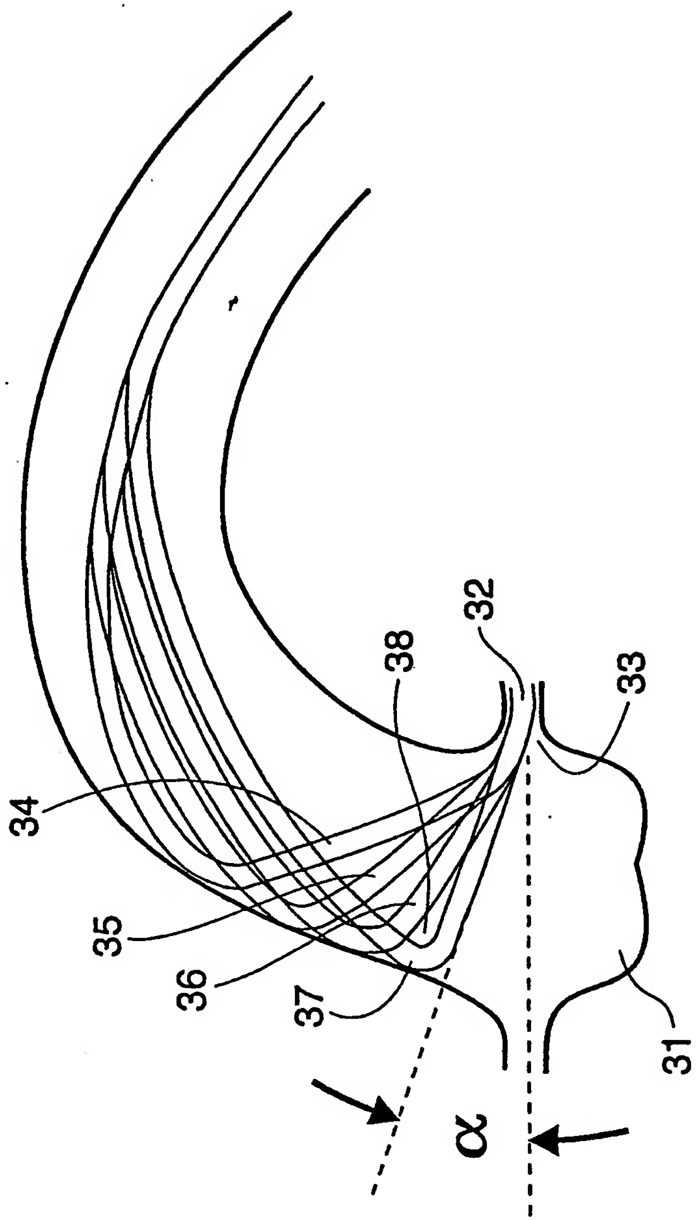

Fig. 4

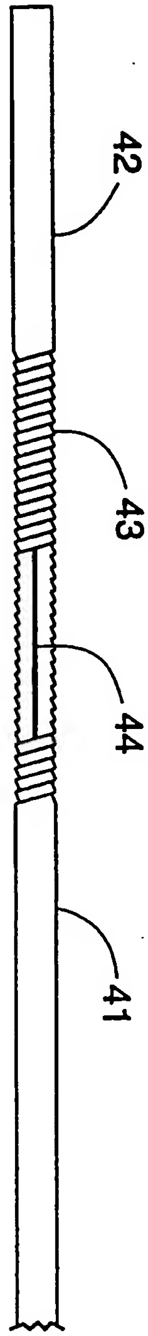

Fig. 5

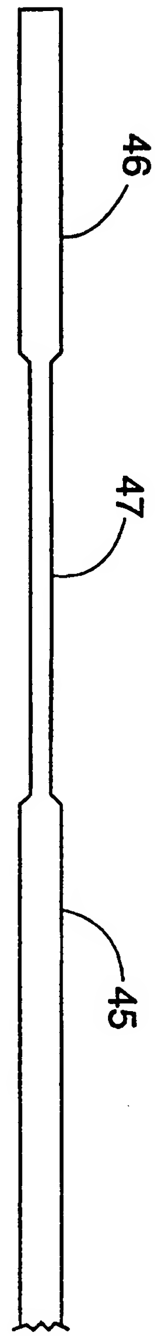

Fig. 6

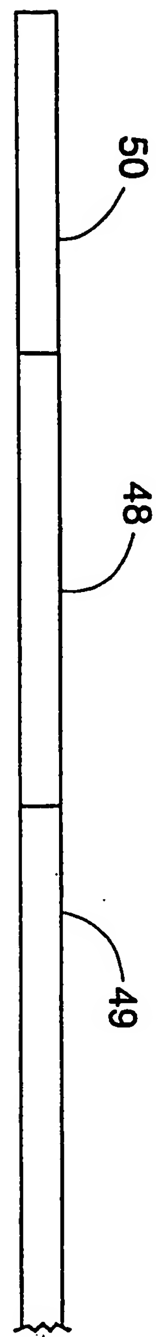

Fig. 7

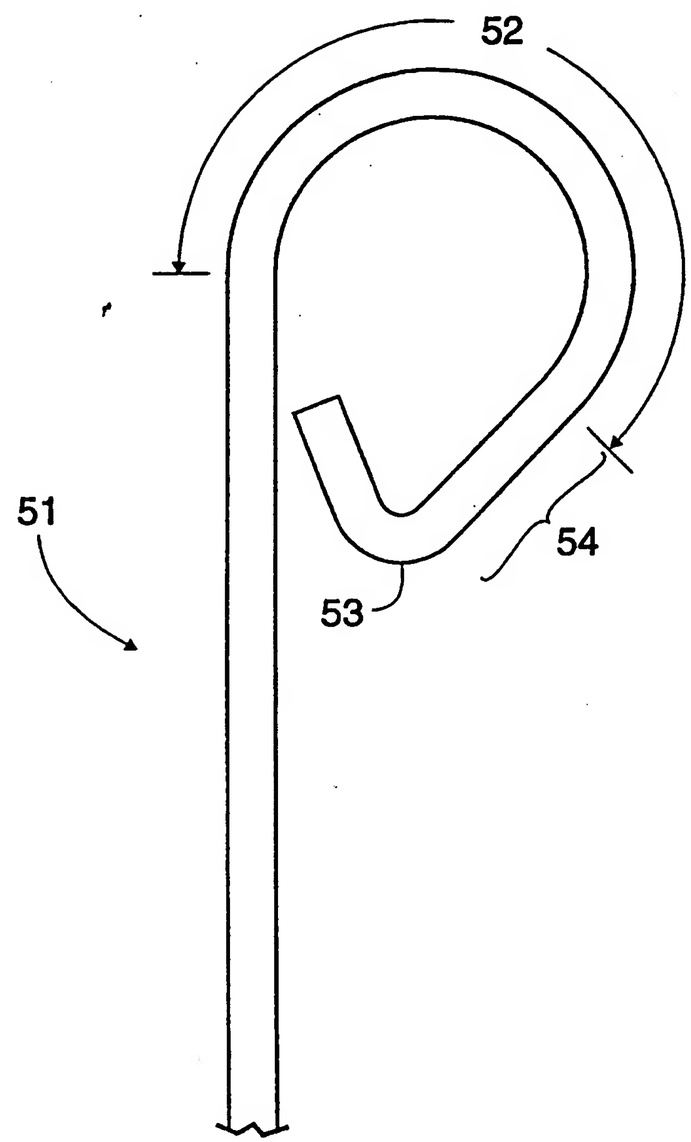

Fig. 8

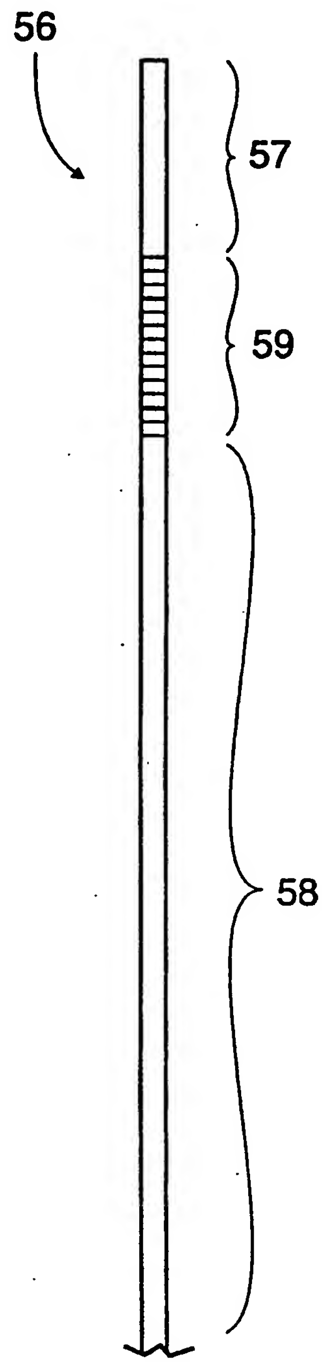

Fig. 9

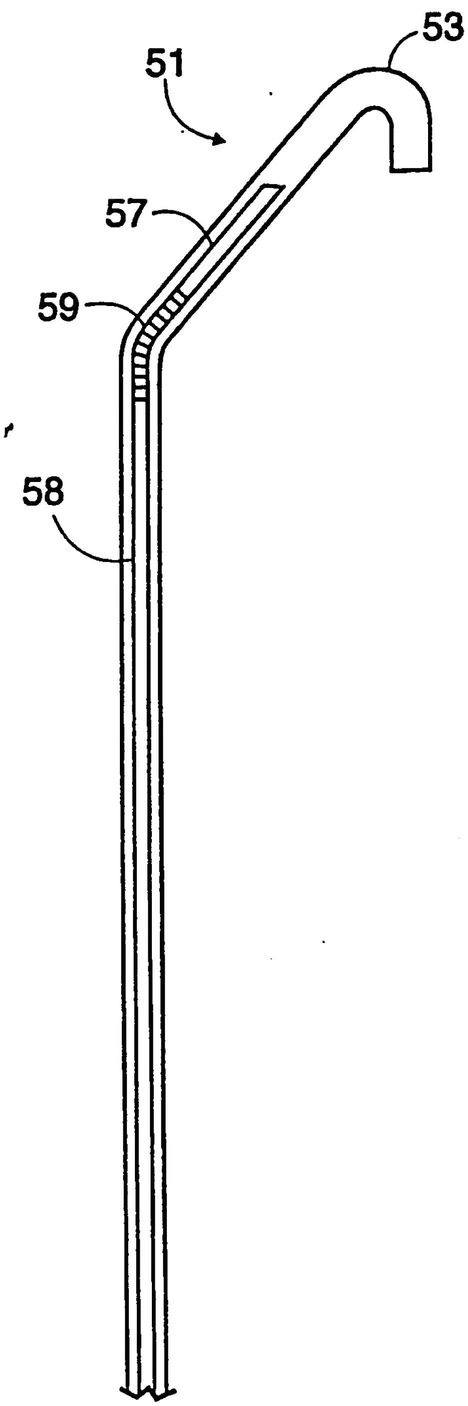

Fig. 10

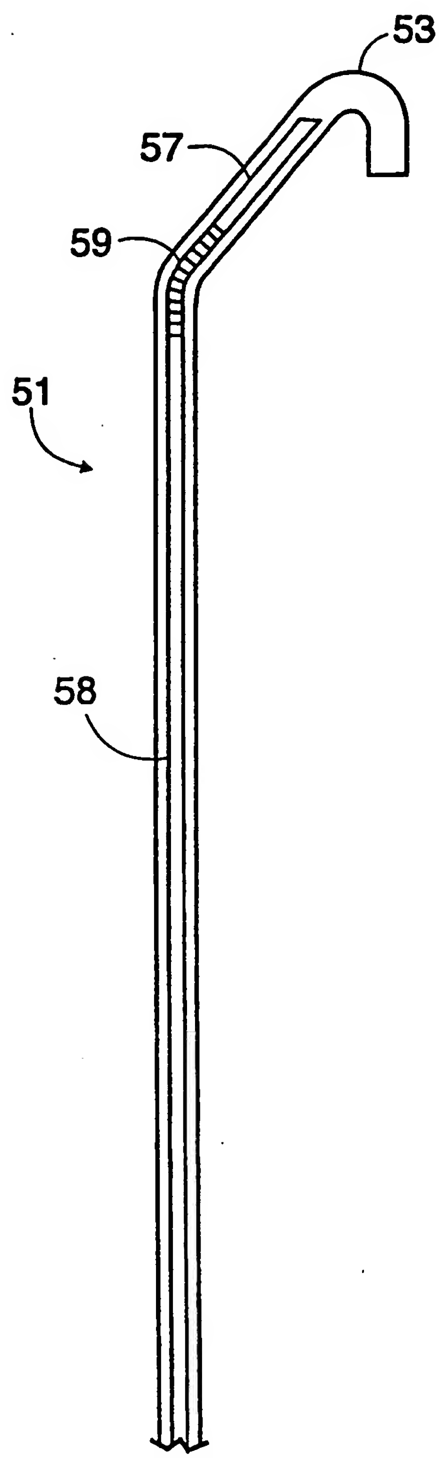

Fig. 11

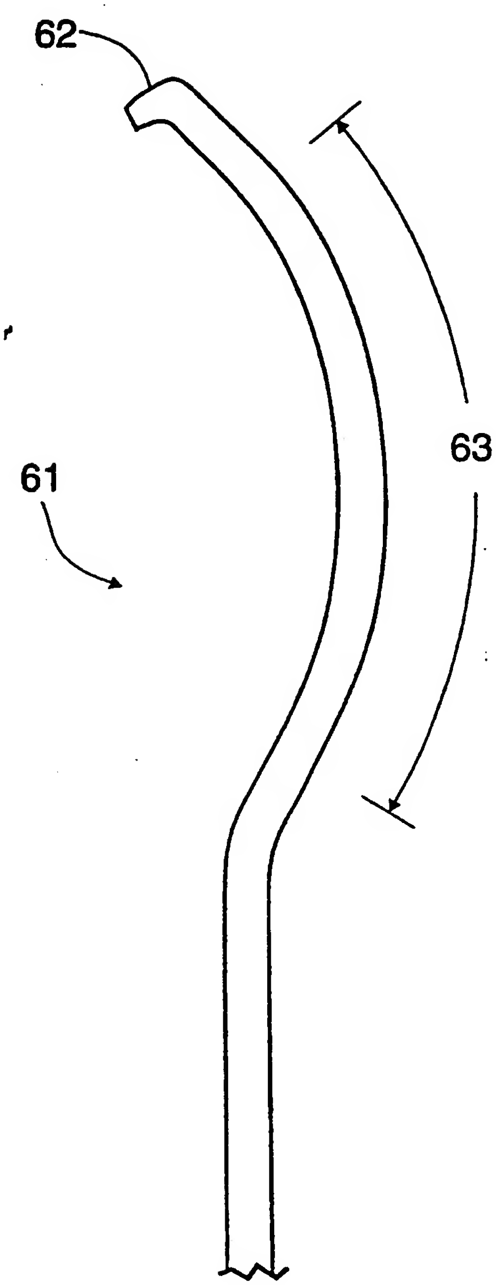

Fig. 12

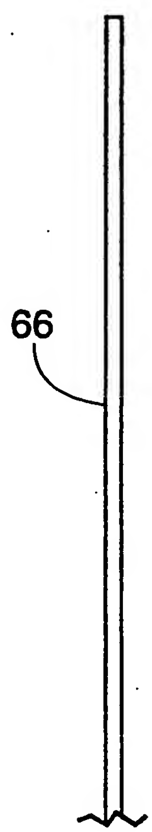

Fig. 13

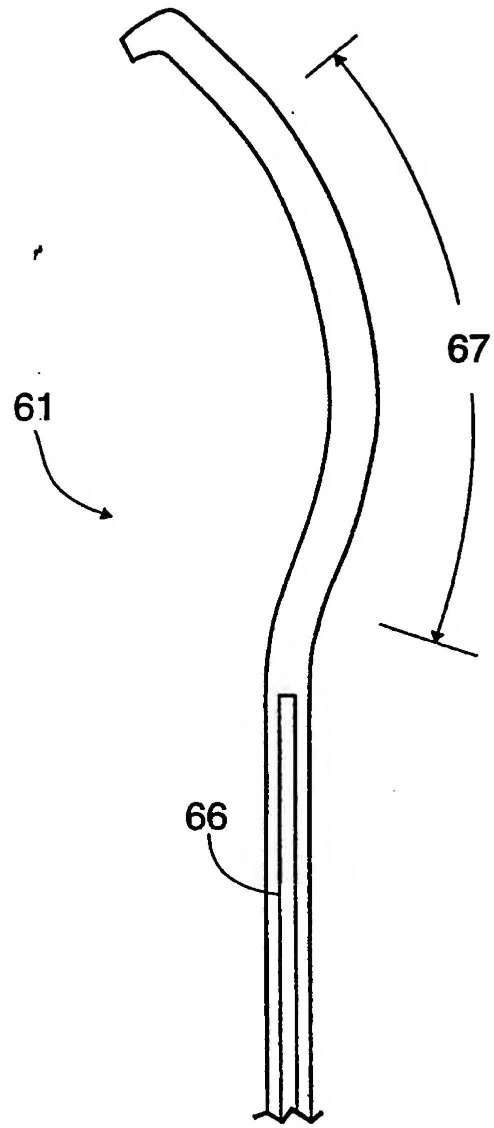

Fig. 14

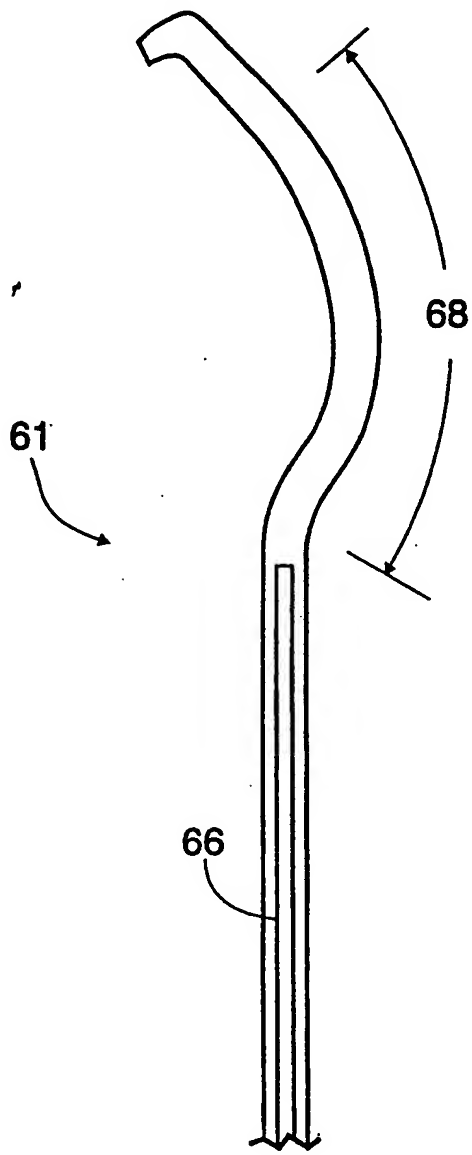

Fig. 15

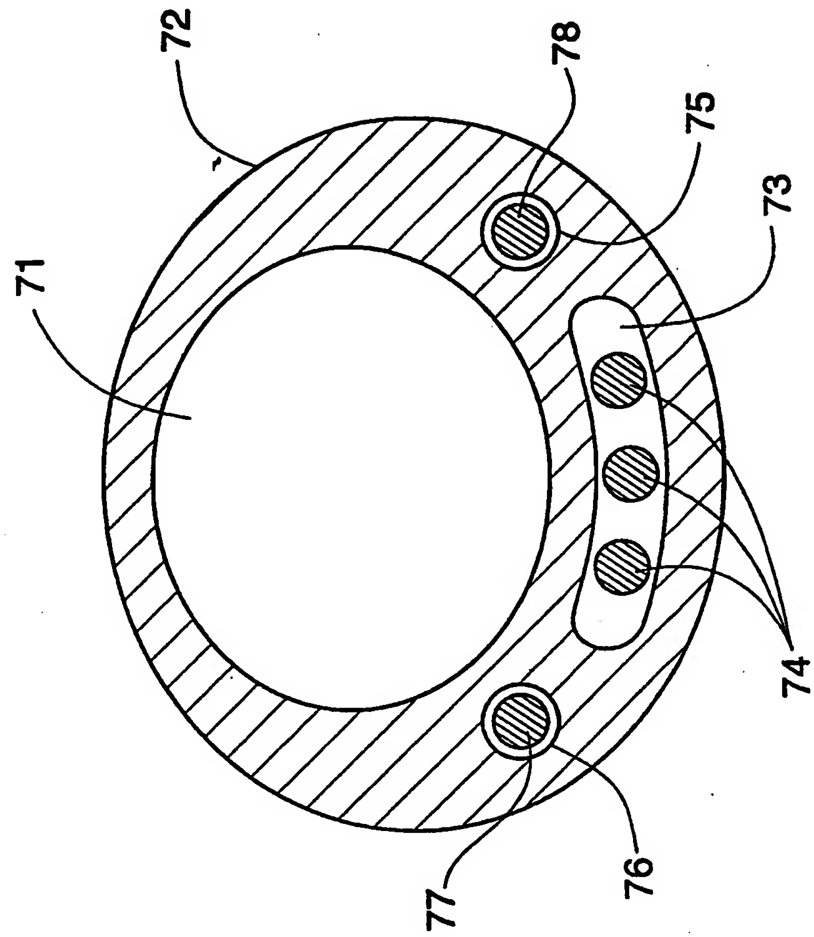

Fig. 16

INTERNATIONAL SEARCH REPORT

Inte: nal Application No
PCT/US 96/08096

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE,A,39 20 707 (FOERSTER ET AL.) 10 January 1991 see abstract; figures 1,2 ---	1-19
A	US,A,4 883 474 (SHERIDAN) 28 November 1989 see abstract; figures 1,9,10 ---	1-19
A	DE,A,43 36 040 (LIEKE) 27 April 1995 see abstract; figures 3,8-10,15 -----	1-19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
11 September 1996	24.09.96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Michels, N

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter nal Application No
PCT/US 96/08096

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A-3920707	10-01-91	NONE	
US-A-4883474	28-11-89	AU-B- 604722	03-01-91
		AU-A- 7558887	21-01-88
		EP-A- 0253606	20-01-88
DE-A-4336040	27-04-95	NONE	